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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,548	11/28/2000	Stephen R. Quake	3153/1G638US2	8333

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EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,548

Applicant(s)

QUAKE ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-62 and 67-69 is/are rejected.
- 7) ☒ Claim(s) 63-66 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67 – 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 67 – 69 recite the limitation "target loops". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 – 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Lipshutz et al. (U.S. Pat. No. 6,043,080 A). Lipshutz et al. teach an apparatus comprising: a loop channel, which essentially comprises a recirculation of fluid flow between a reaction chamber and a pump, communicating with at least one service channel, such as a channel connecting the reaction chambers; a microvalve separating the loop channel from the service channel; and a pump associated with the loop channel (see col. 2, lines 56 – 65; col. 27, line 64 – col. 30, line 9). Lipshutz et al. teach the incorporation of peristaltic pumps (see col. 28, lines 18 – 30).

Lipshutz et al. further teach the incorporation of a number of microvalves for controlling fluid flow within the device (see col. 29, lines 58 – 66). Lipshutz et al. teach the incorporation of a detection region (see col. 4, lines 11 – 41; col. 11, lines 39 – 47; col. 30, lines 24 – 29). Lipshutz et al. teach that the apparatus may comprise a polymeric or elastomeric material (see col. 15, lines 44 – 64). Lipshutz et al. further teach that the piezoelectric pumps utilized may comprise multiple membranes in series (see col. 28, lines 18 – 30). Lipshutz et al. further teach the incorporation of a transparent detection region (see col. 19, lines 15 – 24). Lipshutz et al. teach that the apparatus may comprise a polymeric or elastomeric layer adjacent to a substrate layer (see col. 15, lines 30 – 64). Lipshutz et al. teach that the elastomeric layer may be adjacent to a transparent substrate layer (see col. 15, lines 30 – 64). Lipshutz et al. teach that the apparatus may comprise different parts, layers, or substrates, wherein the apparatus inherently comprises control lines (e.g., electrical circuitry fabricated into the device) for controlling various features of the apparatus, such as pumps, valves, mixers and sensors (e.g., temperature control elements), etc. (see col. 15, lines 30 – 64; col. 25, lines 36 – 63; col. 27, lines 12 – 67 & col. 28, lines 30). Lipshutz et al. further teach the use of bonding in fabricating the apparatus (see col. 15, lines 4 – 29). Lipshutz et al. teach the use of a controllable valve structure, such as a rupture membrane (see col. 23, lines 1 – 21). Lipshutz et al. teach the incorporation of a diaphragm valve (see col. 16, lines 37 – 67). Lipshutz et al. teach the incorporation of a pressurized fluid system (see col. 21, lines 14 – 52). Lipshutz et al. teach the incorporation of a pneumatic manifold system, which may utilize a gas such as air (see col. 21, lines 21 – 52). The loop channel has a circular configuration (see figure 5A). Lipshutz et al. teach that target molecules, such as polymer sequences, are disposed on the surface of a loop channel (see col. 2, lines 15 – 33; col. 11, lines

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33 – 47). Lipshutz et al. also teach that reagents may be incorporated within the device (see col. 5, lines 1 – 21).

Regarding claims 5 – 9, 26, 27, 29, 33, 36 – 39, 41, 59 and 61, these claims recite process or intended use limitations, such as the presence of target molecules within the loop channel, for example, which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ

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528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 67 – 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. Lipshutz et al. do not specifically teach the number of target loops recited in each of these claims. However, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of a person of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a multitude of loop channels to facilitated an increase in the diagnostic screening capacity of the apparatus of Lipshutz et al.

Allowable Subject Matter

Claims 63 – 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The cited prior art neither teach or fairly suggest the incorporation within the apparatus of Lipshutz et al. a substrate comprising a microtiter plate having microtiter wells, wherein each microtiter well comprises a target molecule patterned thereon; and the microtiter plate is connected to the treatment layer so that at least a portion of the length of each loop channel is sealed by a microtiter well.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Unger et al. teach microfabricated elastomeric valve and pump systems. Spence et al. teach a microfabricated cell sorter for chemical and biological materials.

It should also be noted that claims 1 – 69 appear to be claiming the same invention as that of claims 1 – 69 of copending Application No. 09/875,438. The applicant is advised that if claims 1 – 69 of this application conflict with any of the allowed claims 1 – 69 of Application No. 09/875,438 which are identical, 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. The applicant would be required

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to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. *Application 09/875,438 is currently unavailable for claims comparison*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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